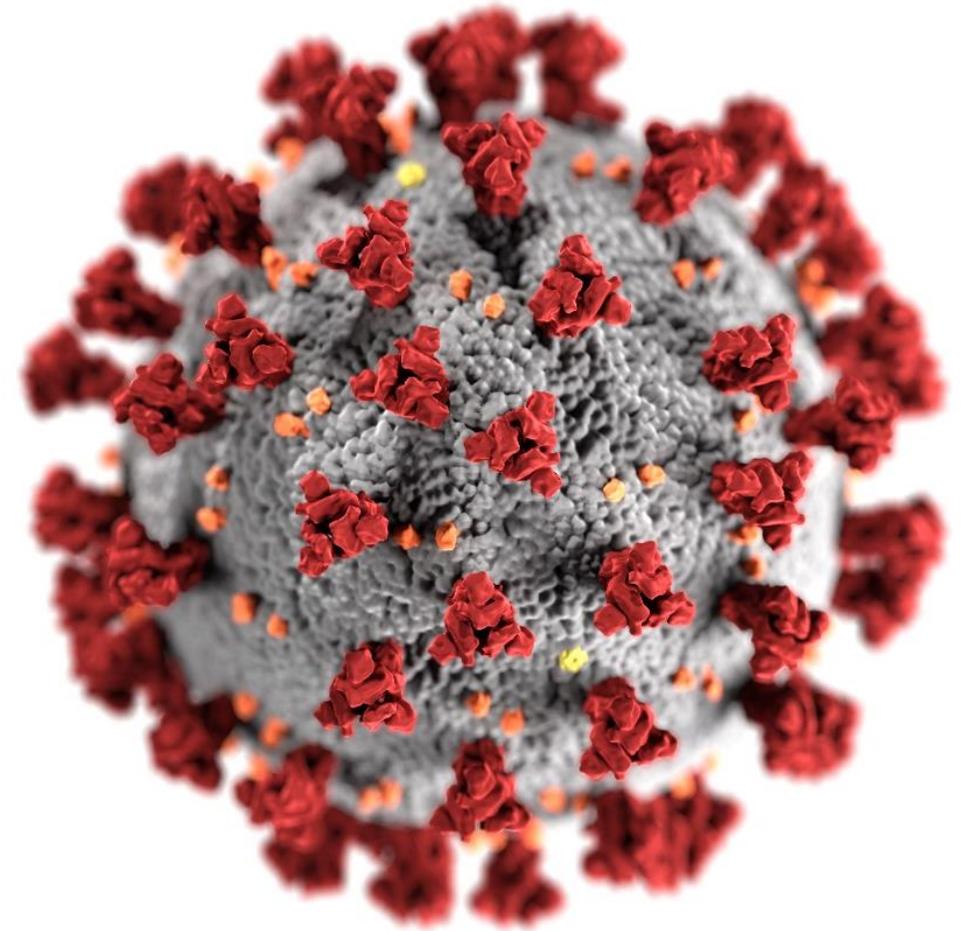


COVID-19 vaccine effectiveness during Omicron for children and adolescents

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ACIP
May 19, 2022



cdc.gov/coronavirus

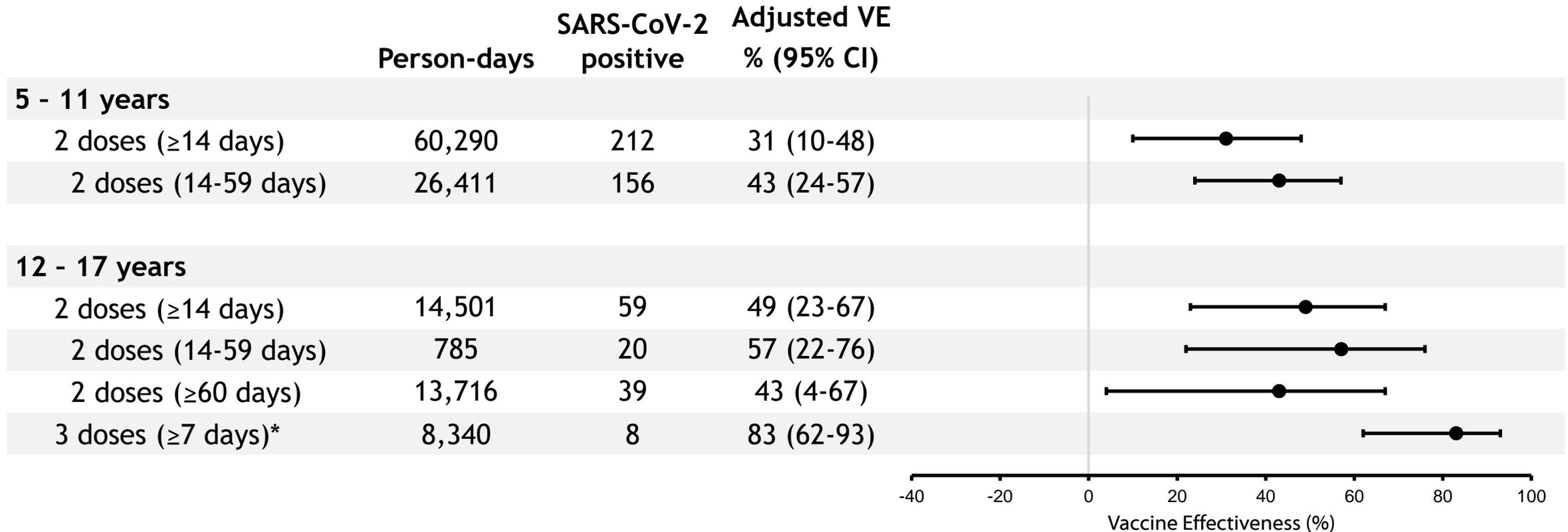
Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT)

- **Design:** Prospective cohort study
- **Population:** Children ages 4 months - 17 years
- **Methods:** Weekly surveillance and self-swab
 - SARS-CoV-2 testing by RT-PCR and whole genome sequencing
 - Electronic surveys during and after SARS-CoV-2 infection
 - Multi-method vaccination documentation
- **Analysis:** Cox proportional hazards model adjusted by propensity to be vaccinated, site, SARS-CoV-2 circulation, and community mask use
 - Timeframe for analysis during local Omicron predominance
 - December 14, 2021 - April 23, 2022



Recruitment includes children of adult participants in a similar study (HEROES-RECOVER) of frontline workers and from the local community

PROTECT: VE against SARS-CoV-2 infection by age group during Omicron variant predominance, Dec 2021-Apr 2022

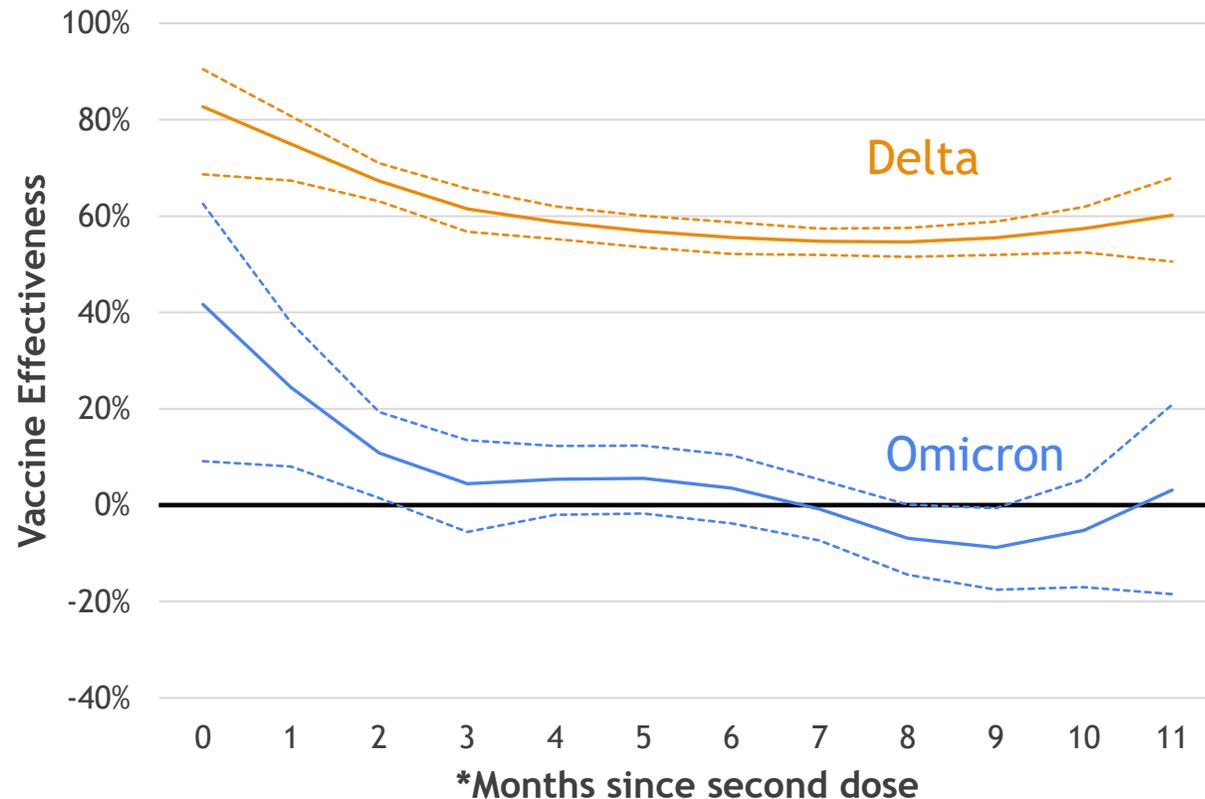


* Median time from vaccination to test was 95 days

Increasing Community Access to Testing (ICATT) Partnership: VE analysis for symptomatic infection

- Nationwide community-based drive-through COVID-19 testing via pharmacies
- Self-reported vaccine history at time of registration for COVID-19 testing; excluded those who did not report vaccination status
- **Design:** Test-negative, case-control analysis
- **Population:** Persons with ≥ 1 COVID-like symptom and nucleic acid amplification testing (NAAT)
- **Adjusted for:**
 - Calendar day, race, ethnicity, gender, site's HHS region, site census tract's social vulnerability index (SVI)
 - **Not** adjusted for prior infection
- **Period:**
 - **Adults:** Tested December 10, 2021 – January 1, 2022, also adjusted for number of underlying conditions and tests, excluded if prior positive test within 90 days (Omicron defined by s-gene target failure)
 - **Children:** Tested December 26, 2021 – February 21, 2022 (Omicron variant increased from 74 to >99% weekly in nationally sequenced specimens)

ICATT: Pfizer-BioNTech 2-dose VE against symptomatic infection by variant and time since 2nd dose receipt, adults ages ≥ 18 years, Dec 10, 2021-Jan 1, 2022



■ VE for 2 doses of Pfizer-BioNTech against symptomatic Omicron infection:

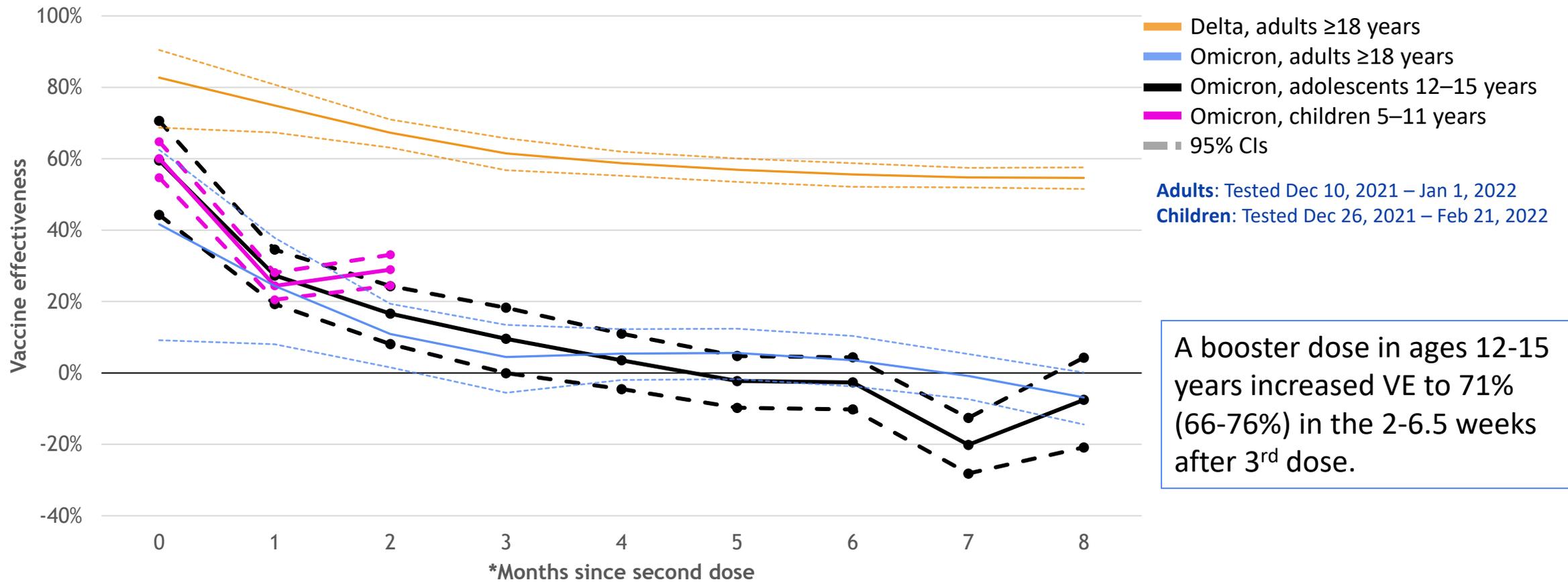
- Starts lower than 2-dose VE against Delta infection
- No longer significant by 3 months after second dose receipt

— VE for Delta
— 95% CI for Delta
— VE for Omicron
— 95% CI for Omicron

*Vaccination dose dates are collected as month and year. Month 0 represents tests in the same month as 2nd dose (at least 2 weeks after 2nd dose). For all months greater than or equal to 1 the value represents the difference between calendar month of test and calendar month of 2nd dose receipt (at least 2 weeks after 2nd dose).

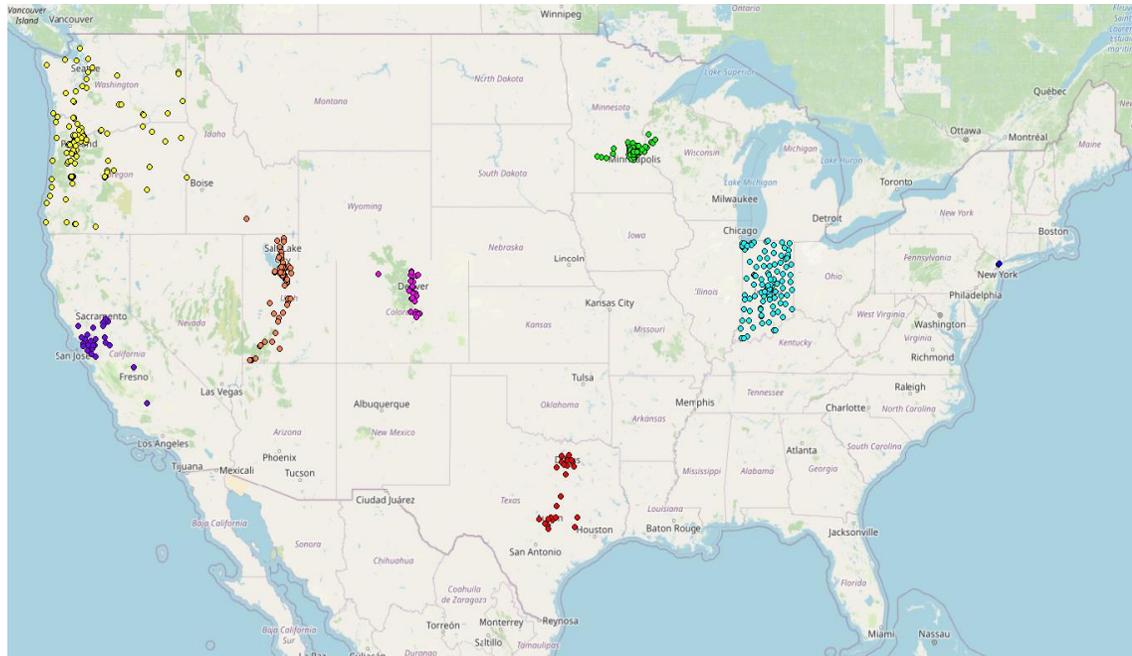
Accorsi EK, Britton A, Fleming-Dutra KE, et al. Association Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the SARS-CoV-2 Omicron and Delta Variants. JAMA. 2022;327(7):639-651. doi:10.1001/jama.2022.0470

ICATT: Pfizer-BioNTech 2-dose VE against symptomatic infection, by age group and variant



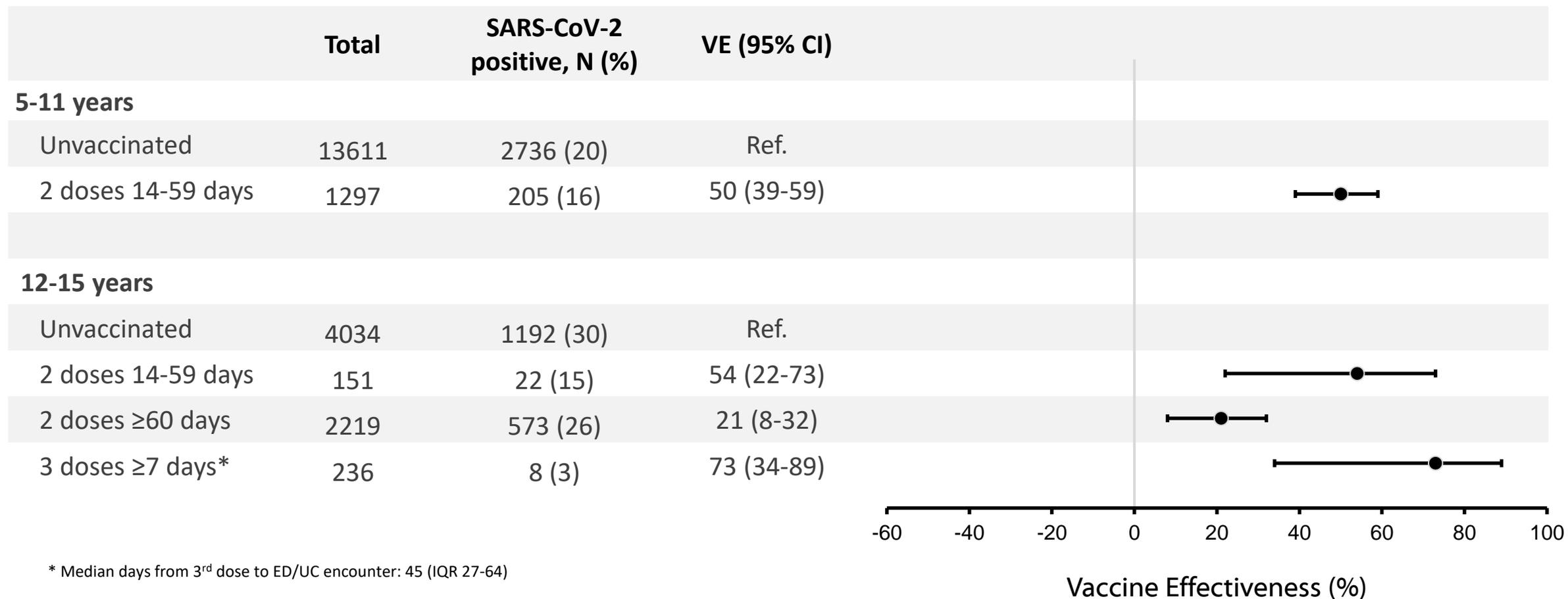
*Vaccination dose dates are collected as month and year. Month 0 represents tests in the same month as 2nd dose (at least 2 weeks after 2nd dose). For all months greater than or equal to 1 the value represents the difference between calendar month of test and calendar month of 2nd dose receipt (at least 2 weeks after 2nd dose).

VISION Multi-State Network of Electronic Health Records



- **Cases:** COVID-like illness (CLI) with positive PCR for SARS-CoV-2 within 14 days before or 72 hours after the admission or encounter
- **Controls:** CLI with negative PCR for SARS-CoV-2
- Delta vs. Omicron determined by time when Omicron predominated in study site (mid-December 2021)
- VE adjusted by propensity to be vaccinated weights, calendar time, region, local virus circulation, and age
- Vaccination documented by electronic health records and state and city registries

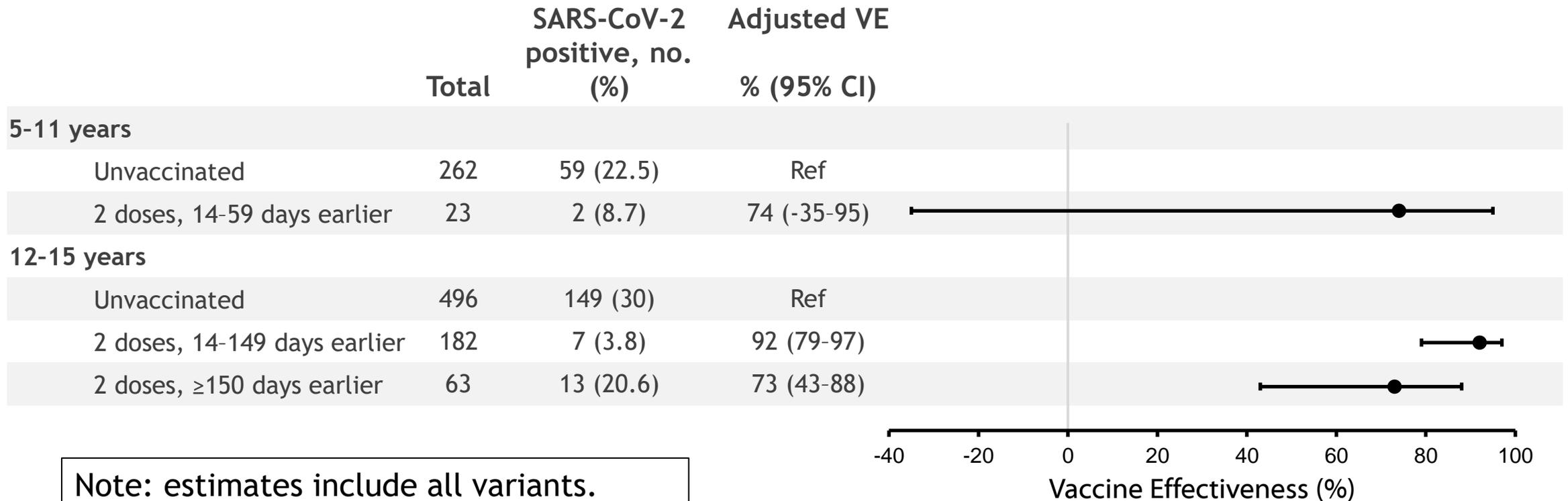
VISION: mRNA VE for ED/UC visits by number of doses and time since last dose receipt for children and adolescents during Omicron, Dec 2021–Mar 2022



* Median days from 3rd dose to ED/UC encounter: 45 (IQR 27-64)

CDC, preliminary unpublished data. Individuals with prior infections excluded. Logistic regression conditioned on calendar week and geographic area, and adjusted for age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying medical conditions, and propensity to be vaccinated
 COVID-like illness: included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms (cough, fever, dyspnea, vomiting, or diarrhea)

VISION: mRNA VE against hospitalization, all variants, ages 5-15 years, Apr 9, 2021-Jan 29, 2022



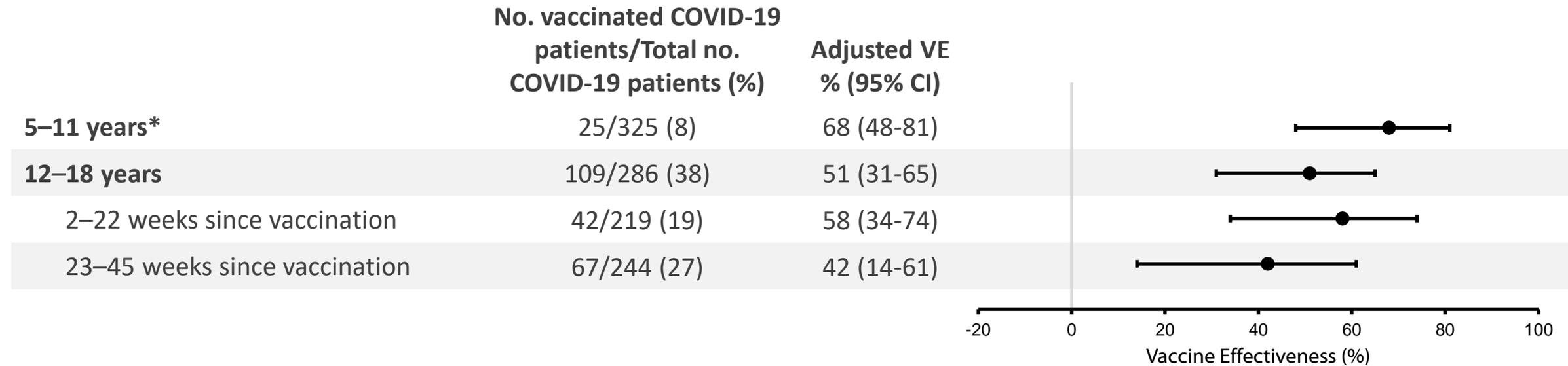
Note: estimates include all variants.

- 5-11 years: 190 (67%) due to Omicron
- 12-15 years: 111 (15%) due to Omicron

Overcoming COVID-19 Methods

- **Design:** Case-control test-negative design
- **Population:** Children and adolescents hospitalized at 31 pediatric medical centers in 23 U.S. states
- **Case status (RT-PCR or antigen)**
 - Cases tested SARS-CoV-2 positive
 - Controls tested SARS-CoV-2 negative
- **Vaccination status (documented or plausible self-report)**
 - Fully vaccinated with Pfizer-BioNTech vaccine (dose 2 is ≥ 14 days prior to illness onset)
 - Or unvaccinated by illness onset
- **Logistic regression to estimate VE against hospitalization (VE_s)**
 - Comparing odds of being fully vaccinated vs unvaccinated in COVID-19 cases and controls
 - $VE_s = 100 \times (1 - \text{adjusted odds ratio})$
 - Adjusting for admission date, hospital region, age, sex, race/ethnicity

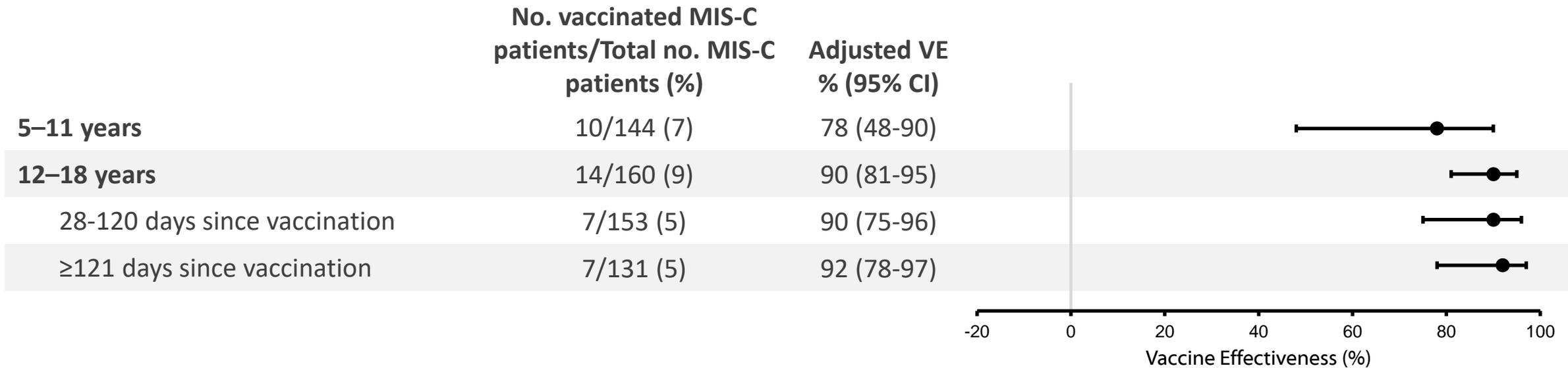
Overcoming COVID-19 platform: VE for 2 doses of Pfizer-BioNTech vaccine against hospitalization, Dec 19, 2021-Apr 27, 2022



*median time from vaccination to hospitalization is 37 days

CDC preliminary unpublished data. Methods from: Price AM, Olson SM, Newhams MM, Halasa NB, Boom JA, Sahni LC, Pannaraj PS, Irby K, Bline KE, Maddux AB, Nofziger RA, Cameron MA, Walker TC, Schwartz SP, Mack EH, Smallcomb L, Schuster JE, Hobbs CV, Kamidani S, Tarquinio KM, Bradford TT, Levy ER, Chiotos K, Bhumbra SS, Cvijanovich NZ, Heidemann SM, Cullimore ML, Gertz SJ, Coates BM, Staat MA, Zinter MS, Kong M, Chatani BM, Hume JR, Typpo KV, Maamari M, Flori HR, Tenforde MW, Zambrano LD, Campbell AP, Patel MM, Randolph AG; Overcoming Covid-19 Investigators. BNT162b2 Protection against the Omicron Variant in Children and Adolescents. N Engl J Med. 2022 Mar 30. doi: 10.1056/NEJMoa2202826. Epub ahead of print. PMID: 35353976.

Overcoming COVID-19 platform: VE for 2 doses of Pfizer-BioNTech vaccine against MIS-C, Jul 1, 2021-Apr 7, 2022



Summary

■ Infection

- 2-dose VE declines quickly in children and adolescents, following similar pattern to adults during Omicron
- A booster dose in adolescents significantly improved VE at least 6 weeks-3 months after the 3rd dose

■ Emergency department/urgent care visits

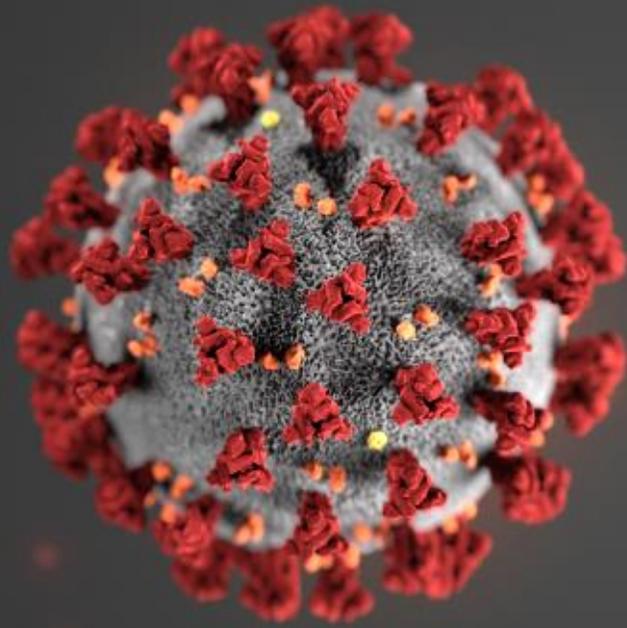
- 2-dose VE was higher for ED/UC visits compared to infection.
 - Declined once >60 days after the 2nd dose for adolescents
- A booster doses in ages 12-15 years significantly improved VE

■ Severe disease: hospitalization and MIS-C

- 2-doses provided protection for both children and adolescents, with some waning evident for hospitalization in adolescents
- Not enough data to assess waning in 5-11 or impact of booster dose in 12-15

Acknowledgements

- Tamara Pilishvili
- Sara Oliver
- Allison Ciesla
- Lauren Roper
- Zach Smith
- Ryan Wiegand
- Site PIs and study staff for ICATT, PROTECT, VISION, and Overcoming COVID
 - Emma Accorsi
 - Amadea Britton
 - Alexandra Dalton
 - Katherine Fleming-Dutra
 - Ashley Fowlkes
 - Samantha Olson
 - Manish Patel
 - Mark Thompson
 - Laura Zambrano



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